| ATTY DOCKET NO. | 1219-021-999 | (500752-999020, P4901P1) | APPLICANT | (Use several sheets if necessary) | APPLICANT | Ronald Pettis, et al. | FILING DATE | June 29, 2001 | 3763 | | STANMINER | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE | IF APPROPRIATE | TO SUBCLASS | TO

	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
-CM	4,886,499	12-1989	Cirelli, et al.			
CN	5,279,552	01-1994	Magnet			
CO	5,582,591	12-1996	Cheikh			
CP	5,848,990	12-1998	Cirelli, et al.			
CQ	6,056,716	05-2000	D'Antonio, et al.			
CR	6,319,224	11-2001	Stout, et al.			
ļ	CO CP CQ	-CM 4,886,499 CN 5,279,552 CO 5,582,591 CP 5,848,990 CQ 6,056,716	-CM 4,886,499 12-1989 CN 5,279,552 01-1994 CO 5,582,591 12-1996 CP 5,848,990 12-1998 CQ 6,056,716 05-2000	CM       4,886,499       12-1989       Cirelli, et al.         CN       5,279,552       01-1994       Magnet         CO       5,582,591       12-1996       Cheikh         CP       5,848,990       12-1998       Cirelli, et al.         CQ       6,056,716       05-2000       D'Antonio, et al.	-CM       4,886,499       12-1989       Cirelli, et al.         CN       5,279,552       01-1994       Magnet         CO       5,582,591       12-1996       Cheikh         CP       5,848,990       12-1998       Cirelli, et al.         CQ       6,056,716       05-2000       D'Antonio, et al.	-CM       4,886,499       12-1989       Cirelli, et al.         CN       5,279,552       01-1994       Magnet         CO       5,582,591       12-1996       Cheikh         CP       5,848,990       12-1998       Cirelli, et al.         CQ       6,056,716       05-2000       D'Antonio, et al.

				FOREIGN	PATENT DOCUMENTS	S				
			DOCUMENT NUMBER	DATE	COUNTRY	- ~	CLASS	SUBCLASS	TRANSL	ATION
									YES	NO
MI	A	CS	WO 94/23777	10/27/1994	PCT					
	T	CT	EP 0 429 842	08/28/1996	EP			<del></del>		
-	<del>                                     </del>	CU	WO 97/21457	06/19/1997	PCT					
m.	TH	CV	WO 00/09186	02/24/2000	PCT					

4:	OW	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)  Agrawal, et al., Pharmacokinetics, Biodistribution, and Stability of Oligodeoxynucleotide Phosphorothioates in
MIH	CW	Mice, Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 7595-7599, September 1991 Medical Sciences
	CX	Autret, et al., Comparison of Pharmacokinetics and tolerance of Calcitonine administered by Intradermal or Subcutaneous Route, Fundamental Clinical Pharmacology, Vol. 3, No. 2, pp 170-171, 1989
	CY	Benoni, et al., Distribution of Ceftazidime in Ascitic Fluid, Antimicrobial Agents and Chemotherapy, Vol. 25, No. 6, June 1984, pp. 760-763
	CZ	Bickers, et al., editors, Clinical Pharmacology of Skin Disease, pp. 57-90, Churchill Livingstone, Inc. 1984
MISH	DA	Bocci, et al., The Lymphatic Route. IV. Pharmacokinetics of Human Recombinant Interferon a2 and Natural Interferon beta Administered Intradermally in Rabbits, International Journal of Pharmaceutics, 32, 1986, pp. 103-110 Elsevier Science Publishers B.V. (Biomedical Division)
MJH	DB	Bronaugh RL, Stewart RF, Congdon ER. Methods for in Vitro Percutaneous Absorption Studies. II. Animal Models for Human Skin. Toxicol. Appl. Pharmacol. 1982 Mar 15;62(3):481-8.
41214	-DC	Callen, Intralesional Corticosteriods, Journal of the American Academy of Dermatology, University of Louisville School of Medicine, pp. 149-151, 1981
	DE_	Corbo M. Liu JC. Chien VW. Transdermal Controlled Delivery of Propranolol from a Multilaminate Adhesive Device. Pharm Res. 1989 Sep;6(9):753-8.
MJH	DF	Cossum, et al., Disposition of the C-Labeled Phosphorothioate Oligonucleotide ISIS 2105 after Intravenous Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 1181-1190, Vol. 26 No. 3, 1993
W57	DG	Cossum, et al., Pharmacokinetics of C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105 after Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 89-94, Vol. 269, No. 1, 1994
	DH	Crooke, et al., A Pharmacokinetic Evaluation of C-Labeled Afovirsen Sodium in Patients with Genital Warts, Clinical Pharmacology & Therapeutics, pp. 641-646, Vol. 56, No. 6, Part 1, December 1994
	DΪ	Firooz, et al., Benefits and Risks of Intralesional Corticosteroid Injection in the Treatment of Dermatological Diseases, pp. 363-370, Vol. 20, No. 5, Clinical and Experimental Dermatology, Blackwell Science Ltd, September 1995
12/14	DJ	Goodarzi, et al., Organ Distribution and Stability of Phosphorothioated Oligodeoxyribonucleotides in Mice, Biopharmaceutics & Drug Disposition, pp. 221-227, Vol. 13, No. 3, John Wiley & Sons Ltd., April 1992

VET 5 3 SUD	띩	Sheet 2 Of 2
MAI	X)K	Haynes, et al., Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets, Anestheiololgy, Vol. 63, Vol. 5. pp. 490-499, Nov. 1985
B TRANSPORT	DL	Jakobson, et al., Variations in the Blood Concentration of 1,1,2-Tricholoroethane by Percutaneous Absorption and Other Routes of Administration in the Guinea Pig, Vol. 41, No. 5, pp. 497-506, Acta Pharmacologizca . et Toxicologica, November 1977
MA	DM	Jarratt, et al., The Effects of Intradermal Steroids on the Pituitary-Adrenal Axis and the Skin, The Journal of Investigative Dermatology, Vol. 62, No. 4, pp. 463-466, 1974
MIH	DN	Kirkpatrick, et al., Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man, Vol. 67, No. 3A, Anesthesiology, September 1987
14574	DO	Leroy, et al., Pharmacokinetics of Ceftazidime in Normal and Uremic Subjects, Antimicrobal Agents and Chemotherapy, Vol. 25, No. 5, pp. 638-642, May 1984
	_DP	McAllister et al., Solid and Hollow Microneedles for Transdermal Protein Delivery. Proceed. Intl. Symp.
		Control. Rel. Bioact. Mater., 26 (Revised July 1999) Controlled Release Society, Inc. pp. 192-193
MIH	DQ	McGugan, et al., Adrenal Suppression from Intradermal Triamcinolone. The Journal of Investigative
17174	DR	Dermatology, Vol. 40, pp. 271-272, Baltimore, MD., 1963 Scott, et al., Toxicity of Interferon, Vol. 282, pp. 1345-1348, British Medical Journal, April 25, 1981
MITH	DS	Sebastien et al., Mircrofabricated Needles: A Novel Approach to Transdermal Drug Delivery, Journal of Pharmaceutical Sciences, Vol. 87, No. 8, August 1998, pp. 922-925
MA	DT	Supersaxo, et al., Recombinant Human Interferon Alpha-2a: Delivery to Lymphoid Tissue by Selected Modes of Application, Pharmaceutical Research, Vol. 5, No. 8, pp. 472-476, August 1998
	DU	Sutherest, Treatment of Pruritus Vulvae by Multiple Intradermal Injections of Alcohol. A Double-Blind Study, Vol. 86, pp. 371-373, British Journal of Obstetrics and Gynecology, May 1979
	DV	Ward, et al., Puritus Vulvae: Treatment by Multiple Intradermal Alcohol Injections, Vol. 93, No. 2, pp. 201-204, British Journal of Dermatology, August 1975
	DW	Wu, et al., Pharmacokinetics of Methoxyflurane after its Intra-Dermal Injection as Lecithin-Coated Microdroplets, Vol. 9, pp. 1-12, Journal of Controlled Release, July 1989
MIH	DX	Zaynoun, et al., The Effect of Intracutaneous Glucocorticoids on Plasma Cortisol Levels, Vol. 88, No. 2, pp. 151-156, British Journal of Dermatology, February 1973

EXAMINER	MA	Hayer	DATE CONSIDERED	3/21/05
----------	----	-------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

	· -				ATTY DOCKET NO. 11219-021-999	(P4901-P		ATION NO 93,746
LIST	OF I	REFERENCES CIT (Use several sheets if		PLICANT	APPLICANT Pettis et al.			
					FILING DATE June 29, 2001		GROUP 3763	
			U.S. P	ATENT DOCU	MENTS			
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS	FILING DATE
MITA	BR	6,319,224	11/20/01	Stout et al.				
PIJH	BS	US 2003/0073609	4/17/03	Pinkerton				

		FOREIGN I	PATENT DOCUMENTS				
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSL	ATION
	<del></del>					YES	NO
L							

	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
MJH B	T Bader M. Influenza vaccine experience in Seattle. Am. J. Public Health. 1980 May;70(5):545
В	Brooks et al. Intradermal administration of bivalent and monovalent influenza vaccines. Ann. Allergy. 1977 Aug; 39(2):110-2
В	Brown et al. The immunizing effect of influenza A/New Jersey/76 (Hsw1N1) virus vaccine administered intradermally and intramuscularly to adults. J. Infect. Dis. 1977 Dec;136 Suppl:S466-71
В	W Crowe Experimental comparison of intradermal and subcutaneous vaccination with influenza vaccinc. Am. J. Med. Technol. 1965 Nov-Dec;31(6):387-96
В	X Foy et al. Efficacy of intradermally administered A2 Hong Kong vaccine. JAMA. 1970 Jul 6;213(1):130
В	Y Glenn et al. Advances in vaccine delivery: transcutaneous immunisation. Exp. Opin. Invest. Drugs 1999, 8(6):797-805
В	formulation, route, and method of administration. Mol. Med. 1998 Feb;4(2):109-18
C.	A Halperin et al. A comparison of the intradermal and subcutaneous routes of influenza vaccination with A/New Jersey/76 (swine flu) and A/Victoria/75: report of a study and review of the literature. Am. J. Public Health. 1979 Dec;69(12):1247-50
C	intradermally or subcutaneously to adults with chronic respiratory disease. J. Infect. Dis. 1979 Aug; 140(2):234-8
C	C McElroy et al. Response to intradermal vaccination with A2, Hong Kong variant, influenza vaccine. N. Engl. J. Med. 1969 Nov 6;281(19):1076
C	Roum. Path. Exp. Microbiol. 1981, 40(1):67-70
C	Payler DK. Intradermal influenza vaccine using Portojet 1976. Br. Med. J. 1977 Oct 29;2(6095):1152
C1	
Co	Kong strain) in man. Bull. World Health Organ. 1969;41(3):507-16
Cl	, , , , , , , , , , , , , , , , , , ,
Cl	
C	Division of Merck & Co., Inc., Whitehouse Station, NJ, pp. 2559-2567
CI	K Sveinsson, 1939, Investigation on the Influence of Insulin and Adrenalin in Rabbits with Alimentary Fatty Liver and Muscles and on the Content of Fat and Sugar in Blood, Oslo, Norway (pp. 66-86)
ANTIN CI	Marian et al. 2001, Acta Biologica Hungarica, 52(1): 35-45

EXAMINER	111/	Hazer	DATE CONSIDERED	3/	21/	25

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE and to respond to a collection of information unless it contains a valid OMB control number. Under the Paperwork Reduction Act of 1995, no persons and the

Substitute for form 1449A/PTO

## **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet of 2

	Complete if Known	R.C.
Application Number	09/893,746	
Filing Date	June 29, 2001	OCT - WIL
First Named Inventor	J. PETTIS etale.	£ A 20
Group Art Unit	3763	LL(10, 2002
Examiner Name	Not Yet Assigned	CEAIT
Attorney Docket Number	7767-173562	"EH RO

					U.S. PATENT DOCUM	MENTS	
Exam Initia		Cite No.	U.S. Patent Doc Number Kind C	Code <sup>2</sup>	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
MI	4	AA	2,619,962	Ī	Rosenthal	12/02/1952	
-		AB	3,814,097	1	Ganderton et al.	06/04/1974	
		AC	3,964,482		Gerstel et al.	06/22/1976	
		AD	4,270,537		Romaine	06/02/1981	
		AE	4,592,753		Panoz	06/03/1986	
		AF	5,003,987		Grinwald	04/02/1991	
		AG	5,098,389		Сарриссі	03/24/1992	
	I	AH	5,156,591		Gross et al.	10/20/1992	
		ΑI	5,250,023	1	Lee et al.	10/05/1993	
	П	AJ	5,279,544		Gross et al.	01/18/1994	
		AK	5,417,662		Hjertman et al.	05/23/1995	
		AL	5,527,288		Gross et al.	06/18/1996	
		AM	5,591,139		Lin et al.	01/07/1997	
		AN	5,801,057	<del></del>	Smart et al.	09/01/1998	
		AO	5,820,622		Gross et al.	10/13/1998	
		ΑP	5,848,991	-	Gross et al.	12/15/1998	
	T	AQ	5,876,582		Frazier	03/02/1999	
		AR	5,879,326		Godshall et al.	03/09/1999	
		AS	5,928,207		Pisano et al.	07/27/1999	
	1	AT	5,957,895		Sage et al.	09/28/1999	
		AU	5,997,501		Gross et al.	12/07/1999	
		AV	6,099,504		Gross et al.	08/08/2000	
	$T^-$	AW	6,334,856	Ві	Allen et al.	01/01/2002	
W	174	AX	6,346,095	Bi	Gross et al.	02/12/2002	

	<del></del>	<del></del>		•	N PATENT DOCU	1	Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Office <sup>3</sup>	Foreign Patent Document  Flice Number Kind Code (if known		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
MIH	AY	CA	2 349 431		Canada	05/25/2000		
	AZ	EP	1 086 718	Al	Europe	03/28/2001		
	BA	EP	1 086 719	A1	Europe	03/28/2001		
	BB	EP	1 088 642	A1	Európe	04/04/2001		
	BC	EP	1 092 444	A1	Europe	04/18/2001		
	BD	wo	96/17648		PCT	06/13/1996		
	BE	wo	96/37155		PCT	11/28/1996		
	BF	wo	96/37256		PCT	11/28/1996		
	BG	wo	99/43350		PCT	09/02/1999		
	вн	wo	99/64580		PCT	12/16/1999		
	Bl	wo	00/67647		PCT	11/16/2000		
	BJ	wo	00/74763	A2	PCT	12/14/2000		
WISH	ВК	wo	02/11669	A2	PCT	02/14/2002		

Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no personal required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known Application Number 09/893,746 INFORMATION DISCLOSURE Filing Date June 29, 2001 STATEMENT BY APPLICANT First Named Inventor J. PETTIS et al. **Group Art Unit** 3763 (use as many sheets as necessary) Not Yet Assigned **Examiner Name Attorney Docket Number** 7767-173562 Sheet of

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
MIH	BL	E. AUTRET et al., Therapie 1991, 46 : 5-8.	
	вм	BRESSOLLE et al., "A Weibull Distribution Model for Intradermal Administration of Ceftazidime", Journal of Pharmaceutical Sciences, Vol. 82, No. 11, November 1993, pps. 1175-1178.	
	BN	HENRY et al., "Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery", Journal of Pharmaceutical Sciences, Vol. 87, No. 8, August 1998, pps. 922-925.	
	во	KAUSHIK et al., "Transdermal Protein Delivery Using Microfabricated Microneedles", Oct/Nov 1999 (1 page).	
	ВР	BURKOTH et al., "Transdermal and Transmucosal Powered Drug Delivery", Critical Review™ in Therapeutic Drug Carrier Systems, 16 (4), (1999), pps. 331-384.	
MH	BQ	MCALLISTER et al., "Three-Dimensional Hollow Microneedle and Microtube Arrays", Conference: Solid-State Sensors and Actuators Transducers-Conference, 1999; 10th; Vol. 12, pp 1098-1103.	
<del></del> -			
		·	

Examiner	MI Haye	Date	3/21/05
Signature	They war	Considered	3/ 27 / 23

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

VENABLE

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.